

REMARKS

Claims 1-31 were pending in this application. Claim 3 has been withdrawn by the Office as being directed to non-elected subject matter. With entry of this response, claims 3, 16, 17, 27, and 30 are cancelled, without prejudice or disclaimer to the subject matter contained therein; claims 1, 5-15, 18-26, and 31 are amended; and claims 32-35 are added. Thus, claims 1-2 and 4-15, 18-26, 28, 29, and 31-35 are pending. Support for these new claims and claim amendments is found throughout the specification and claims as originally filed, for example, at pages 3-15 and 23-26. Thus, no new matter has been added by this amendment.

Correction to Restriction Requirement

The Examiner issued a corrected restriction requirement, asserting that claims 1-31 are drawn to the following five allegedly separate and distinct inventions.

Group I: Claims 1-2 and 4-31, drawn to compound of general formula shown in claim 1 wherein the distribution agent is a triazine or formula 1, composition and method of use, classified in class 544, subclasses 180 and 196; and class 514, subclasses 241 and 242.

Group II: Claims 1-7 and 27-31, drawn to compound of general formula shown in claim 1 wherein the distribution agent is a pyrimidine or quinazoline, composition and method of use, classified in class 544, subclasses 283 and 284; and class 514, subclasses 256 and 258.1.

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Group III: Claims 1, 4-7, and 27-31, drawn to compound of general formula shown in claim 1 wherein the distribution agent is not a triazine or diazine and the nitrogen containing aromatic ring is quinoline or pyridine, composition and method of use, classified in class 546, subclasses 152 and 268.1; and class 514, subclasses 311 and 345.

Group IV: Claims 1-2, 4-[sic], and 27-31, drawn to compound of general formula shown in claim 1 wherein the distribution agent is a pyrimidine or a quinazoline, and the nitrogen containing aromatic ring is not quinoline or pyridine, composition and method of use, classified in various classes and subclasses depending upon the choice of nitrogen containing group and the distribution group.

Group V: Claims 1-2, 4-[sic], and 27-31, drawn to compound of general formula shown in claim 1 not provided for in invention I-IV, composition and method of use, classified in various classes and subclasses depending upon the choice of nitrogen containing group and the distribution group.

Office action, pages 2-3.

Applicants confirm their election of Group I, with traverse for the reasons already made of record in response to the previous restriction requirement.

In addition to the restriction requirement, the Examiner again contends that the application, "contains claims directed to the following patentably distinct species: quinoline, pyridine, pyrimidine, generic diazines, benzamides, and

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triazine." Office Action, page 4. Applicants are required to elect one of these species for examination. *Id.* Applicants again note that elected Group I is already drawn to a compound wherein the distribution agent is a triazine. Thus, Applicants see no need for a further election of species. However, to be fully responsive to the requirement, Applicants elect triazines for examination, with traverse for the reasons already made of record in response to the previous election of species requirement. Claims 1-2 and 4-15, 18-26, 28, 29, and 31-35 read on the elected species. Applicants note that the Examiner has indicated that claims 1-31 are generic. Applicants respectfully remind the Examiner that if the elected species is found allowable, pursuant to M.P.E.P. § 803, the search should be expanded to include additional allowable species.

Claim to Priority

On June 20, 2002, Applicants filed a Claim for Priority under 35 U.S.C. § 119, to French Patent Application No. 01 00204, filed January 9, 2001. A certified copy of that French priority document was filed with the Claim for Priority. Applicants respectfully request that the Examiner acknowledge receipt of the certified priority document in this patent application.

The Claims Are Not Indefinite

The Examiner rejected claims 1-2 and 4-31 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the reasons listed below. Office Action, pages 8-9.

The Examiner rejected claim 1 (and claims 5, 9, and 19) as indefinite for reciting "thio radical" and "oxy radical." Applicants have amended the claims to recite "thiol" and "hydrooxy," as suggested by the Examiner.

The Examiner rejected claims 5-26 as indefinite for reciting "compounds" because the claim from which these claims depend recites "a compound." Applicants have corrected the rejected dependent claims so they are consistent with the base claim. The dependent claims now recite "The compound according to claim . . ."

The Examiner rejected claims 16, 17, and 27 as indefinite for claiming a method or process that does not set forth any positive steps. Applicants have canceled these claims and rewritten them in proper form as added claims 32-34.

The Examiner rejected claim 30 as indefinite for reciting "radiation" as part of a composition. Applicants have canceled claim 30 and rewritten it in proper form as added claim 35. The new claim includes radiation as a step in the method, but not as part of a composition.

The Examiner rejected claim 31 as indefinite for lacking a therapeutically effective amount. Applicants have amended the claim to recite "a therapeutically effective amount."

The Examiner rejected claim 18 for reciting "novel." Applicants have deleted the term from the claim. The Examiner also rejected claim 18 as indefinite because there was a subscript missing for R_3 . Applicants have made the appropriate correction.

In view of the above amendments and remarks, Applicants respectfully request that the Office withdraw the rejection under 35 U.S.C. § 112, second paragraph.

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The Claims Are Enabled

The Examiner rejected claims 1-2 and 4-31 under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled. Office Action, pages 9-12. The Examiner acknowledges that the claims are enabled for triazines having thiol, hydroxy, or amino radicals as substituents. But the Examiner contends that the claims are not enabled for thiol, hydroxy, or amino radicals that are substituted with halogen groups. According to the Examiner, the specification does not teach one of skill in the art how to selectively perform the halogenation of these groups when other competing reactive groups are also present in the compound. *Id.*, at 10. The Examiner asserted that such halogenations are not an art-recognized process and "the quantity of experimentation needed would be an undue burden." *Id.*, at 11.

Applicants respectfully disagree. In traversing the rejection, Applicants note that the relevant inquiry for enablement is whether one of skill in the art could make or use the invention from the disclosure in the specification, coupled with information known in the art, without undue experimentation. See M.P.E.P. § 2164.01; *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Moreover, a patent need not teach, and preferably omits what is well known in the art. See M.P.E.P. § 2164.01, and cases cited therein.

Applicants contend that one of skill in the art, using the teachings of the specification and the knowledge in the art, would know how to make and use the presently claimed compounds without undue experimentation. Halogenation reactions are routine in the art. The Examiner does not dispute this fact. Rather, the Examiner is concerned with the ability of a practitioner to specifically target

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the halogenation reaction to a particular substituent. Applicants submit that this type of selective halogenation is also routine in the art. The skilled artisan is familiar with a variety of protecting groups and methods of their use that prevent halogenation at some parts of a compound while permitting the halogenation reaction to proceed at a targeted substituent group. The protective groups are then easily removed following the targeted halogenation step. Although some experimentation might be performed to identify an optimal protecting group or desirable sequence of reaction steps, such experimentation is not undue. Moreover, a considerable amount of experimentation is permissible, so long as it is routine.

In addition, Applicants note that the application, as filed, is presumptively enabled. In challenging the presumptively enabled patent application, the Examiner has only made conclusory statements about what might or might not be possible in a halogenation reaction. This is entirely insufficient to rebut the presumption of enablement. The Examiner must come forward with objective evidence on the record to support an enablement challenge. As of yet, there is no objective evidence on the record to support the Examiner's position. Thus, the Examiner's position is untenable.

For these reasons, Applicants contend that the present claims are enabled and respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 112, first paragraph.

The Claims Do Not Lack Utility

The Examiner rejected claims 16, 17, and 27, under 35 U.S.C. § 101, as allegedly lacking utility. According to the Examiner, these claims recite methods

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but do not set forth any steps for using the methods. Applicants have canceled these claims and rewritten them as added claims 32-34. The added claims recite the steps for practicing the claimed methods. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 101.

The Claims Are Not Obvious

The Examiner rejected claims 1-2, 4-9, 11-15, 17-27, and 31 as allegedly being obvious over Daeyaert et al (U.S. Patent No. 6,150,360). Office Action, pages 13-14. According to the Examiner, Daeyaert describes "several trisubstituted triazines, which include generically compounds of [sic] claimed in the instant claims." *Id.*, at 13. The Examiner acknowledged, however, that Daeyaert does not teach any of the compounds recited in the present claims. *Id.*, at 14. The Examiner contended, however, that the publication "teaches the equivalency exemplified examples [sic] of trisubstituted core, shown on col. 9 and Table 2 and Table 3." *Id.* From this, the Examiner concluded it would have been obvious "to make compounds variously substituted [sic] the triazine ring as permitted by the reference and expect resulting compounds (instant compounds) to possess the uses taught by the art in view of the equivalency teaching . . ." *Id.*

Applicants respectfully traverse this rejection. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify or combine reference teachings in the manner proposed by the Office. See M.P.E.P. § 2143. The suggestion or motivation must be found in the prior art, not in Applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 20

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U.S.P.Q.2d 1438 (Fed. Cir. 1991). Moreover, the suggestion to combine or modify the prior art teachings must be clear and particular. See *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999).

The Examiner must satisfy this burden by showing some objective teaching in the prior art that would lead one of ordinary skill in the art to modify the prior art in the manner proposed by the Office. *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992)(emphasis added). And the prior art must provide one of ordinary skill in the art with the motivation to make the proposed molecular modifications needed to arrive at the claimed compounds. See *In re Lalu*, 747 F.2d 703, 705, 223 U.S.P.Q. 1257, 1258 (Fed. Cir. 1984). The mere fact that the references can be modified does not render the result obvious unless the prior art also suggests the desirability of the combination. See M.P.E.P. § 2143.01 citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

Applicants contend that the Office has failed to establish a *prima facie* case of obviousness. A generic formula, like that described by Daeyaert, does not by itself necessarily render a compound encompassed by that formula obvious. See *In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994). In *Baird*, the court noted that the generic formula of a diphenol structure encompassed more than 100 million different diphenols. Consequently, the court found no suggestion in the reference to select the particular combination of variables in that formula that would give rise to the claimed compound (bisphenol A). Indeed, as the court observed, the reference appeared to teach away from using bisphenol A by focusing on more complex diphenols as "preferred" or "optimum." *Id.* at 382-83, 29 U.S.P.Q.2d at 1552.

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Emphasizing that one must evaluate a reference "not only for what it expressly teaches, but also for what it fairly suggests," the Federal Circuit considered the vast number of diphenols encompassed by the generic diphenol of the reference, coupled with the clear preference for diphenols other than that claimed by Baird, and concluded that the prior art did "not teach or fairly suggest the selection of bisphenol A." *Id.*, at 383. Thus, the Federal Circuit reversed the Board's holding of obviousness under §103.

Similarly, Daeyaert describes tens of thousands of potential combinations of substituents to yield at least hundreds of thousands of different compounds. Yet Daeyaert provides no guidance to one of skill in the art to pick and choose from among these tens of thousands of potential combinations to derive the presently claimed compounds. At best, Daeyaert guides one of skill in the art by teaching "particular", "more in particular," "preferred," and "special" groups of substituents. Again, the list of preferred and special substituents is lengthy and provides for thousands of possible combinations. Yet none of these combinations of "preferred" or "special" substituents yields a compound that renders the present claims obvious. As in *Baird*, the only guidance provided by the cited prior art actually teaches away from the presently claimed compounds. There is no teaching or suggestion in Daeyaert that would motivate the skilled artisan to modify the teachings of Daeyaert to achieve the presently claimed compounds.

Finally, with respect to the Examiner's "equivalency" argument, Applicants contend that Tables 2 and 3 in Daeyaert do not teach that the listed compounds are equivalent. In fact, Daeyaert reports that the compounds exhibit significant

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physical differences, depending on the substituents employed. In particular, Applicants note that the melting points of the compounds (in the last column of the table) vary significantly from one compound to the next (from a low of 152°C to a high of 333°C). For example, Compound Nos. 4 and 32 (column 2 of the table) are both listed as Example No. "B2." By changing a few of the substituents around in this sample, the melting point changes from 235-236°C to 153-154°C. Clearly these are not "equivalent" compounds. Thus, the Examiner has not provided any teaching suggesting that the substituent combinations described by Daeyaert can be equivalently substituted from one compound to the next. Moreover, listing several compounds as interchangeable for one purpose will not establish their equivalency for all purposes. See *In re Jezi*, 396 F.2d 1009, 1012, 158 U.S.P.Q. 98, 99-100 (C.C.P.A. 1968).

In the absence of some other teaching, Applicants contend that there is no motivation to modify Daeyaert to derive the presently claimed invention. The Examiner has simply not pointed to any clear and particular teaching that would have led one of ordinary skill in the art to pick and choose from among the tens of thousands of different substituent combinations described in the art to derive the specific compounds recited in the present claims. At best, it may have been obvious to try every possible combination of substituents described in the art. However, as the Examiner is well aware, obvious to try is not the standard. See M.P.E.P. § 2145(X)(B). Consequently, Applicants respectfully request that the rejection be withdrawn.

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CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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